No. 10-972

IN THE

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

SUN PHARMACEUTICAL INDUSTRIES, LTD.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF

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I. INTRODUCTION

Sun's opposition essentially ignores the express holding of the panel, which announced a new bright-line rule: "obviousness-type double patenting" bars a patent for an otherwise separately patentable new use of a previously patented composition, even when that new use is *not* obvious, whenever it was merely disclosed, but not claimed, in the earlier composition patent. As confirmed by the four-judge dissent from denial of en banc review, that new rule contradicts a century of precedent, conflicts with the patent statute, and will now undermine sound patent policy through its effect on researchers, the PTO, patent applicants, and litigants. Although Sun advances several arguments to avoid the question squarely presented by the Federal Circuit's express ruling, none has merit. This Court, which has not addressed the frequently arising double patenting doctrine since the Patent Act became law in 1952, should grant review to set the doctrine back on its proper footing.

II. ARGUMENT

A. The Panel's New Bright-Line Rule Is, and Had to Be, Independent of Sun's Disputed Factual Allegations

From its restatement of the Question Presented forward, Sun's principal effort to avoid the panel's express ruling is to inject factual allegations that formed no basis for that ruling and, given the procedural posture, could not have. Sun argues that the originally discovered antiviral use of gemcitabine, which was described and claimed in the

'614 patent, was not a "viable" utility because gemcitabine was too "toxic." Opp. 8-9. Thus, according to Sun, there was only one invention-supporting utility for gemcitabine—to treat cancer. *Id.* at 9-10. But this disputed factual theory was not—and could not have been—the basis either for the district court's decision on *summary judgment* or for the Federal Circuit ruling on review of that decision. Both courts accepted, as they had to given the procedural posture of the case, that the antiviral use was a patent-supporting utility. The new rule announced by the Federal Circuit, applying double patenting to bar claims to *all* disclosed utilities, assumes the existence of *multiple* adequately disclosed utilities, as Sun acknowledges in quoting the rule. *Id.* at 28 (quoting Pet. App. 12a).

This was hardly accidental. During oral argument, when Judge Bryson observed that Sun's viability contention "would require us to do a fair amount of something that sounds an awful lot like fact finding," Sun's counsel stated, "I don't suggest you do it." C.A. No. 2010-1105 Argt. Rec. 23-24 min. The panel then expressly decided the case on the basis of its new ("simpler," "more elegant") bright-line rule (*id.*), completely avoiding the disputed factual and legal issues over the antiviral utility.[1] It

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[1] The only court to have tried the issue found that the original disclosure of gemcitabine and its antiviral activity did enable a patentable utility. Pet. App. 70a-72a. Moreover, Sun's "viability" theory, equating patent-law utility with FDA approval and commercialization for human therapeutic use, is legally incorrect. Drugs too toxic to be approved by the FDA and commercialized may nonetheless satisfy the utility

is the expressly stated new rule, which *assumes* an adequate antiviral utility, that now confronts the PTO, patent applicants, and litigants as precedent.

B. Sun Offers No Meaningful Response on the Merits

Lilly's petition at 20-24 cited decades of Federal Circuit and CCPA precedent that conflicts with the bright-line rule, much of which was also cited by the dissenting judges at the Federal Circuit. Pet. App. 136a-138a. *Sun offers no response to this authority.* Sun does address this Court's decision in *Miller v. Eagle Manufacturing Co.*, 151 U.S. 186 (1894), but what Sun says effectively confirms that *Miller* contradicts the panel's new rule. Opp. 29-30.

Sun has to label the key passage from *Miller* as "dictum," which, according to Sun, does not address "obviousness-type" double patenting. *Id.* That response implicitly accepts that the *Miller* passage undermines the Federal Circuit's new rule, and it also is unsustainable on its own terms. The *Miller* passage stated the rationale of this Court's decision and, by focusing on what has previously been *claimed* rather than on what has previously been *disclosed*, provided the framework for obviousness-type double patenting for the next century.

Sun's second response to *Miller* is to repeat Sun's factual allegations that, here, the composition

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requirement. *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995); *In re Anthony*, 414 F.2d 1383, 1394-95 (CCPA 1969).

patent had only one cognizable utility—"to combat cancer." Opp. 30. As already explained, however, the Federal Circuit's express ruling correctly assumes the contrary. Sun's two responses to *Miller*, in short, confirm that it cannot be squared with the panel's express ruling.

Concerning the Federal Circuit's decisions in *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline, PLC*, 349 F.3d 1373 (Fed. Cir. 2003), and *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008), Sun merely parrots the panel's discussion of those two cases. Opp. 26-28. The new rule would warrant review even if *Geneva* and *Pfizer* lent it some support, but in fact the rule is radically new. Sun simply ignores the Petition's explanation of why those decisions plainly do not support the new bright-line rule, *e.g.*, that *Geneva* involved a single-utility composition patent and *Pfizer* involved a first patent that concededly *claimed* the use again claimed in the second patent. Pet. 24-27. Tellingly, the author of *Geneva*, Chief Judge Rader, joined the dissent in this case, decrying the panel's rule as a departure from precedent.

Addressing the new rule's conflict with the statute, Sun argues that double patenting exists to prevent an unjustified "timewise extension of the right to exclude." Opp. 31-32. That simply begs the question. The measure of whether such an unjustified extension exists is whether a party is attempting to obtain two patents on the same invention or an obvious variation thereof. Lilly's central point, following *Miller* and decades of like precedent and the statute, is that a mere disclosure

in an earlier patent does not "patent" what is there disclosed. Yet, the Federal Circuit has here barred a patent on a new use of a previously patented composition without ever finding that the earlier patent claimed the new use (it did not) and regardless of whether the new use was obvious from the earlier-claimed composition and different use (the Indiana district court found this new use nonobvious after a full trial). Pet. App. 105a-120a. Sections 100(b) and 101, 35 U.S.C., make the nonobvious new use separately patentable, and the federal courts have no power to create a common law doctrine that conflicts with statutory standards enacted by Congress. *See* Pet. 28-33.

C. The Fundamental Change to Double Patenting Warrants Review

Sun advances a host of arguments for why the double patenting issue is not important enough to warrant review. None has merit.

The question of when two inventions are sufficiently different to support the issuance of separate patents, which is at the core of the double patenting doctrine, pervades all aspects of modern patent practice. That question guides filing decisions made by thousands of patent applicants. It dictates the PTO's decisions under 35 U.S.C. § 121 about when multiple inventions disclosed in a single application should be divided into separate patents.[2]

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[2] The PTO procedures in this regard embodied in the Manual of Patent Examining Procedure §§ 802, 806.05(h) (8th ed. rev. 8, July 2010), which regard compositions and materially different

It affects whether pending applications and previously issued patents should be required to have their terms shortened to avoid double patenting (by "terminal disclaimers") and whether two patents with the same expiration date must remain commonly owned. Large numbers of patents and applications are affected by the standards for double patenting.

Sun argues that there are not "recent cases in the lower courts involving similar legal issues or fact patterns." Opp. 23. Not so. For example, a mere six weeks ago, Teva presented a double patenting argument that "rel[ied] on facts closely resembling those analyzed by the Federal Circuit in the . . . *Sun Pharmaceuticals* and *Pfizer* cases, as well as in *Geneva*." *OSI Pharms., Inc. v. Teva Pharms. USA, Inc.*, Nos. 09-185, -186-SLR, 2011 WL 892349, at *1 (D. Del. Mar. 11, 2011). In any event, the issue is critically important to the biotechnology and pharmaceutical industries, as reflected by the amicus briefs filed here by PhRMA and the Biotechnology Industry Organization, which depend on long-term investments based on stable and predictable patent laws. The Federal Circuit's restrictive new rule will cut off patent terms, stifle disclosure, and impair the high-risk investments on which the medical progress produced by these industries depends. Sun's assertion that a special patent-limiting rule should apply to pharmaceutical patents (Opp. 1-2, 26-27), making such patents

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methods of using them as separate inventions, will have to be revamped if the new bright-line test is left standing.

worth *less*, is neither supported by any authority nor sensible.

The doctrine of double patenting, including obviousness-type double patenting, arises in cases and at the PTO with considerable frequency. Sun admits that without guidance from this Court for the last hundred years, the Federal Circuit has addressed the "substance" of double patenting over 100 times. Opp. 19 n.4. With the present decision cutting the doctrine adrift from its statutory moorings, review by this Court is now needed.

Contrary to Sun's submission, statutory changes that now set patent terms as 20 years from filing do not materially diminish the importance of the issue. Even aside from the substantial number of still-enforceable patents with terms of 17 years *from issuance* (like this patent), Sun's suggestion applies only in the context of applications derived from a common ancestor application that claim the same effective filing date. That is not remotely the extent of the effect of the Federal Circuit's new rule. This case, and others like it, involve different original applications with different effective filing dates, where the change in patent term will have no effect. And even under the 20-years-from-filing regime, an inventor is entitled to a full term running from the filing of its new application after its new discovery of a nonobvious new use of a compound that is the subject of an earlier-filed application. The Federal Circuit rule denies such inventors that entitlement.

The significance of that entitlement is further magnified by variations in patent term resulting

from patent term adjustment under 35 U.S.C. § 154. Even if filed on the same date, the prosecution of different applications in practice takes different amounts of time due to the particular issues raised. Thus, the amount of time restored to the patent term will be different. One recent estimate suggests that nearly 80% of issued patents receive some term adjustment because of the large backlog of applications awaiting examination at the PTO.[3] It is therefore vital to preserve the statutory entitlement to file separate applications, contrary to Sun's casual suggestion that applicants should just insert new discoveries into still-pending older applications and cede part of their patent term.

What is and is not covered by the double patenting doctrine remains significant for yet another reason. Where the doctrine applies, it continues to require patents claiming obvious variations of the same invention not only to expire at the same time but also to remain commonly owned. *See In re Van Ornum*, 686 F.2d 937, 945 (CCPA 1982) (noting that prevention of harassment by multiple assignees underlies the doctrine of double patenting); *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009) ("even after the Uruguay Round Agreements Act, double patenting doctrine still serves to prevent a proliferation of patent monopoly rights for nearly identical subject matter [that] could be separately owned and independently enforced") (citation omitted). Thus, the doctrine of double

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[3] *See* http://www.patentlyo.com/patent/2010/01/patent-term-adjustment-statistics.html

patenting will continue to be important long into the future.

Although Sun argues that review in this case is not warranted because patentees can avoid the risk of double patenting by taking certain steps, the simple fact is that Sun's proposals all involve giving up rights specifically provided for by the patent statute. For example, Sun suggests that Lilly should have filed a "terminal disclaimer" on its anticancer-use '826 patent. Opp. 20. But that would have required Lilly to give up part of the statutory patent term for this second patent. As set forth in Lilly's petition at 8-10, the invention of using gemcitabine to treat cancer was a separate, nonobvious invention, discovered by a separate inventive entity more than a year after the earlier compound and antiviral-use invention, and lawfully claimed in a separate patent. There is no reason why Lilly should have to surrender part of the independent patent term guaranteed by statute.

Sun also suggests that Lilly should have sought to claim the cancer utility in the application that led to the '614 patent. Opp. 21. Nothing in the statute, however, either in 1984 or today, requires an inventor to include all his separately patentable inventions in a single application. *Miller* did not so hold, 151 U.S. at 198, and Congress, in sections 100(b) and 101, has specifically sanctioned *separate* patents on nonobvious new uses of existing compounds.

Sun's contention that Lilly should not have added the one paragraph about the cancer utility in the application that led to the '614 patent (Opp. 21)

demonstrates the dramatic negative policy consequences of the panel's new rule. A patent on an invention of great importance to the public in treating pancreatic cancer has been declared invalid as a matter of law under circumstances where it would have been entirely valid and enforceable had the new invention been *concealed* from the readers of the earlier patent. This is the antithesis of the public disclosure policy underlying the Patent Act.

The concealment course Sun now suggests likely will become the norm if the panel's bright-line rule is left standing. In the future, patent practitioners must refrain from informing the public of anything more than a single use for each newly discovered composition lest they forfeit otherwise independent patent rights in newly discovered uses. This result should not stand. At the very least, this Court should seek the views of the Solicitor General about how the new rule will affect the patent system.

D. The Question Presented Is Properly Before this Court

Sun argues that the question presented is somehow not properly before this Court. Opp. 14-16. That argument is entirely devoid of merit.

The petition squarely challenges the express ruling of the panel, asking whether the panel's bright-line rule conflicts with a vast body of hitherto well-settled double patenting precedent and with the statute. Where, as here, that rule was announced as the rationale for rejecting Lilly's contention that there is no double-patenting bar to the '826 patent, a challenge to the rule is properly presented. *See*

Lebron v. Nat'l R.R. Passenger Corp., 513 U.S. 374, 379 (1995) (issues pressed or passed upon below may be raised in this Court); *United States v. Williams*, 504 U.S. 36, 41 (1992) (same).

More specifically, Lilly appealed from the district court's double-patenting invalidation of its patent. In response, Sun argued that there was a bright-line rule supported by "75 years" of precedent that any use disclosed in the specification could not be later claimed because of double patenting. Sun C.A. Br. 3-4, 30. In reply, Lilly explained that "[s]uch a bright-line test, however, has *never* been the law in this Court," and in fact "[c]onflicts with [e]stablished [p]recedent." Lilly C.A. Reply Br. 1, 3, 4-14. And once the panel adopted its bright-line rule, Lilly challenged it before the en banc court (Lilly En Banc Pet. 6-8), and four judges agreed with Lilly, without the slightest suggestion of any preservation issue (Pet. App. 134a-141a).

Sun quotes Lilly's en banc petition as stating that, "'[h]aving correctly described the law of obviousness-type double patenting in its opinion, the Panel then failed to apply it.'" Opp. 15. But Lilly plainly was *not* arguing that the panel merely failed to apply correct precedent to the facts before it, but that the panel abandoned that precedent in favor of creating an entirely new rule that conflicts with long-standing precedent. Lilly En Banc Pet. 6-8. As noted, the *four* dissenting judges on the Federal Circuit, *in response to Lilly's arguments*, agreed and explained that "[t]he law of double patenting is contrary to the panel's holding[,]" and "[t]he panel

opinion violates a vast body of precedent." Pet. App. 136a, 138a.

Sun's contention that Lilly did not assert that *Geneva* or *Pfizer* were incorrect is a red herring. Lilly's position was and is that those two decisions did *not* apply the panel's bright-line rule. *See* Pet. 24-27; Lilly C.A. Reply Br. 15-17. It was the panel in this case, at Sun's urging, that interpreted those two cases as warranting the imposition of a bright-line rule that never before existed.

Of course, once the panel articulated its new rule, Lilly was entitled to elaborate on the arguments against that rule as long as, as here, the arguments support the same claim that there is no such double-patenting bar. *Lebron*, 513 U.S. at 379. In fact, between its panel and en banc briefing, Lilly invoked all the arguments made in the petition for certiorari, giving the Federal Circuit a full opportunity to consider these arguments. *See, e.g.*, Lilly C.A. Opening Br. 21-22 (35 U.S.C. § 120); Lilly En Banc Pet. 9-10 (§ 120), 11 (§ 100(b)), 11-14 (35 U.S.C. § 103). The question presented in the petition for certiorari is properly before this Court.

III. CONCLUSION

For all the above reasons, the Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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